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August 13, 1997

Mr. Jeffrey Sampson
Philip Morris U.S.A.
Research Center
PO Box 26583
Richmond, VA 23261-6583

RE: Pricing Estimates for Philip Morris LIMS

Dear Jeff:

The following prices are very crude estimates of what I believe the Philip Morris LIMS will cost. Realize of course that I do not set prices nor have any association with any LIMS vendor. These prices are based on "ball park" estimates from previous quotes that I have seen for systems that approximate the size you will need.

The prices are for:

System Cost
Installation (Implementation)
Validation
Training
Software escrow

\$750,000	(capitol)
\$300,000	} Expense items
\$250,000	
\$ 75,000	
\$ 5,000	

An Oracle license, if needed, will depend on the system finally chosen. Some vendors, such as LabSystems, include Oracle runtime version included with the system purchase price plus some needed tools. For your purposes, I believe that it will be necessary to negotiate a full Oracle site license for Philip Morris since the vendors generally add a surcharge to the license fee and also because Philip Morris will have more clout negotiating directly with Oracle. Philip Morris, should they become an Oracle licensee, will be an important reference for Oracle.

Instrument interfacing may be crudely estimated at \$1,000 to \$1,500 per instrument. However, your GC s and LC s are common instruments connected by a HP Data Station and very easily interfaced. These HP instrument characteristics are well known to the major LIMS vendors and the interface cost should be significantly below the \$1,000 per instrument. It is entirely possible to negotiate a fixed price for all of the GC and LC instruments as a package.

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The instruments "unique" to your industry may be more difficult and costly to integrate into the LIMS system. A complete description of each in the RFP will obtain quotes for this aspect.

Pilot System verses Full Implementation

There are a number of pros and cons that the entire LIMS Team must consider in deciding which direction to go. There is no simple right or wrong answer and as long as we decide by considering openly and with full discussion of the available options, the decision will be the correct one for Philip Morris.

First of all, I recommend that we include in the requirements document, a requirement that the vendor post a "performance bond" to insure that the system purchased will meet our specifications or the money is refunded. The cost of this, ultimately, is borne by Philip Morris since the vendors simply add it on to the price. This performance bond should cost roughly 5% of the total system cost.

Almost all of the vendors will essentially "pilot" the system before full implementation anyway. The vendor will identify a number of key labs and put the system, as described in the functional specifications, into these labs first. This is done for a number of reasons not the least of which is to let users in all of the labs get the feel of the system (about four weeks I think is proper). Following this, a "gap analysis" should be done to identify where the pilot system does not fit with what the other labs need and/or does not fit with what the users anticipated.

This scenario should ensure that the system chosen meets the requirements of Philip Morris and that the system behaves as expected. The system will not be validated at this point so it could not be used for shipment of a regulated product but that was never the purpose of a pilot system.

By purchasing the full system initially, the size of the system makes Philip Morris eligible for discounts on licensing fees. To put this into prospective, the costs given above total approximately \$1,400,000. Lets assume a 200 user system. The costs vary VERY ROUGHLY linearly but, without the discounted licensing, the full system might cost 15% to 25% more (almost \$2,000,000). Therefore, a "pilot" system for 20 users may cost \$200,000 - \$250,000, for an unvalidated system. Many of the costs, however, such as training and in some respects, validation, are independent or almost independent of the number of users. My guess would be about \$325,000 - \$350,000 for your 20 user system. Validation would not be done on the "pilot" system. If this "pilot" system were the only one purchased and then Philip Morris decided to go on with purchase of the full

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system, it is my belief that a significant portion of this money will be lost. It may be an area for negotiation but I don't think that it makes sense to do it this way.

I would suggest that with a properly written and comprehensive Request for Proposal, we include not only the performance bond recommended above, but include very specific milestones which must be met before the vendor may proceed with the next step. This "pilot" operation would simply be made one of the milestones and we would specify which labs and how many users would be on this pilot system. The payment schedule would also be in accordance with the number of user licenses bought. This may provide the best alternative to matching the concern of many for the functionality of the LIMS to an initial large scale implementation.

Existing LIMS plus New LIMS

It has been mentioned as an alternative to keep using and validate the existing two LIMS and adding the new LIMS as a third. At some point in time, additional functionality would be added to the new LIMS to take over the role(s) of the older LIMS. Additional licenses would be purchased as the "system" grows. There is absolutely nothing wrong with this approach and may, in fact, suffice for a short term solution. The current system must be critically examined to see that there is a rugged audit trail, sufficient safeguards to ensure that source code can not be changed arbitrarily, a change control system is in place, complete documentation for the entire system is written, and the system is validated. Validation costs probably would be in line or slightly above that of a commercial system.

Unfortunately the current system was not a focus of my last visit so I am unable to comment on other aspects of this approach. I did hear many favorable comments from the users about the current systems and there is no reason whatsoever to believe that the system would be difficult to validate, if this is the path chosen by the LIMS task force. I believe that this should be a topic for discussion at some of the JAD meetings. Perhaps we should schedule a JAD meeting with the LIMS team on this very issue. It's probably worthwhile to do this prior to any of the other JAD meetings because it affects all of the other operations.

Very truly yours,



Martin Goffman, Ph.D.
Principal